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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,019	11/21/2001	Peter T. Pugliese	Prov.#1-3	9491

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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,019

Applicant(s)

PUGLIESE, PETER T.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: the term "solubilizing agent" is apparently misspelled as "solubizing agent". Appropriate correction is required.

Claim 10 is objected to because of the following informalities: the term "chitosan" is apparently misspelled as "chitsan". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the bioflavonoid oligomeric proanthrocyanidins" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soudant et al. (US Patent 5,436,230), Majeed et al. (US Patent 5,804,596), Lotte (JP7-61927), Kuppusamy et al. (Biochem. Pharmacol. 1992; 44(7):1307-1315), Sekiya (US Patent 5,776,906), and Koulbanis (US Patent 4,288,433) in view of De Simone (WO 98/01128) and Gennaro (Remington's Pharmaceutical Science, 18th ed., 1990, page 1305 and 1307).

Soudant et al. teaches a topical emulsion composition containing lipolytic agents such as caffeine and carnitine (See col. 2, line 25-38; also claims 21, 26, and 27). Soudant et al. also teaches the composition contains surfactant and a solubilizing agent (See col. 3, line 45 – col. 4, line 16). Soudant et al. also teaches a method of slimming the body by topically applying the said emulsion composition onto the skin (See claim 11).

Majeed et al. teaches forskohlin is useful in a method of promoting lean body mass and promoting weight loss (See the abstract). Majeed et al. also teaches the amount of forskohlin to be 1 – 40% of the composition (See the abstract).

Lotte teaches quercetin is useful for prevention and therapy of obesity (See the abstract).

Kuppusamy et al. teaches that both fisetin and quercetin are useful as a lipolytic agents because of the similar structure of both agents (See the abstract).

Sekiya teaches genistein is useful in a method of promoting fat degradation (See claims 4-6).

Koulbanis teaches theophylline in the amount of 0.1 to 5% of the composition is useful as a slimming or anti-cellulite action (See col. 1, line 10-14; also col. 2, line 7-66; and claims 1-3).

The references do not expressly teach that the employment of all the actives together in one composition or method. The references do not expressly teach the employment of the up to about 5% of quercetin, up to about 5% of fisetin, up to about 5% of genistein, up to about 2% of coleus extract, or up to about 1.5% of L-acetyl carnitine into the composition. The references do not expressly teach that the employment of natural gum such as xanthan gum and carageenan. The references do not expressly teach that the employment of gelling agents such as methoxycellulose, ethoxycellulose, carboxycellulose, acyanacrylate, polyvinylpyrrolidone, or chitosan.

De Simone teaches L-acetyl carnitine is useful in a method of treating obesity (See claims 2 and 4).

Gennaro teaches that methylcellulose and carrageenan are well known to be useful as a gelling agent (See page 1305, col. 2 and 1307, col. 2).

It would have been obvious to one skill in the art when the invention was made to employ all the actives together in one composition or method. It would have been obvious to one skill in the art when the invention was made to employ up to about 5% of quercetin, up to about 5% of fisetin, up to about 5% of genistein, up to about 2% of coleus extract, or up to about 1.5% of L-acetyl carnitine into the composition. It would have been obvious to one skill in the art when the invention was made to employ natural gum such as xanthan gum and carageenan and gelling agents such as

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methoxycellulose, ethoxycellulose, carboxycellulose, acrylamide, polyvinylpyrrolidone, or chitosan into the topical emulsion composition.

One of ordinary skill in the art would have motivated to employ all the actives together in one composition or method because all the actives herein are known to be useful as a fat degradation promoting agents or lipolytic agents. Combining two or more agents which are known to be useful to promote fat degradation individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Based on the cited prior art, employing the fat degradation promoting composition in a method of treating cellulite would have been reasonably expected to be useful since promoting fat degradation would decrease the local accumulation of fat and treating cellulite thereby.

One of ordinary skill in the art would have motivated to employ up to about 5% of quercetin, up to about 5% of fisetin, up to about 5% of genistein, up to about 2% of coenzyme Q10, or up to about 1.5% of L-carnitine into the composition because all the actives herein are known to be useful as a fat degradation promoting agents or lipolytic agents. Combining two or more agents which are known to be useful to promote fat degradation individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Furthermore, the optimization of result effect parameters (e.g., amount of the actives) is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have motivated to employ natural gum such as xanthan gum and gelling agents such as polyvinylpyrrolidone into the topical emulsion

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composition because these agents are known to be useful as gelling agents to increase the viscosity of the composition. Therefore, employing these gelling agents would have been reasonably expected to be useful to formulate a gelling emulsion composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
February 9, 2002


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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